IVD'S INFLECTION POINT

AN ECOSYSTEM ANALYSIS OF *IN VITRO* DIAGNOSTICS IN INDIA

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Abstract

India's diagnostic ecosystem is at an inflection point. The convergence of low-cost engineering, advances in assay chemistry, and algorithmic interpretation is reshaping how biological information is generated and used across the health system. This convergence has reduced per-test costs, expanded disease coverage, and enabled diagnostics to move closer to the patient - supporting decentralised care delivery across primary, secondary, and community settings.

But the real opportunity is not cheaper tests. It is **more biology per rupee** - greater clinical insight, earlier detection, and better decision-making for every unit of public or private spend. In a system marked by workforce constraints, high out-of-pocket expenditure, and uneven access, diagnostic value needs to be defined by informational yield, not test volume.

This whitepaper outlines how India can align policy, procurement, and capital to prioritise biological yield and downstream outcomes. For policymakers, it highlights the levers required to shift diagnostics from input-driven purchasing to impact-oriented design. For investors, it reframes diagnostics as data-rich platforms that enable scalable, preventive, and longitudinal care. And finally, for incumbents, it outlines how it can expand their businesses in brand new, blue ocean markets.

The Three New-Age IVD Categories

A shift from new generation of technologies is shifting diagnostics from episodic, lab-centric interventions to continuous, decentralised, and decision-supportive systems. These innovations can be broadly understood across three overlapping categories: **point-of-care chip systems, multi-omics diagnostics, and AI-augmented assistive technologies**. Each represents a distinct pathway to increasing biological yield per rupee - by compressing infrastructure, expanding signal depth, or amplifying clinical capacity.

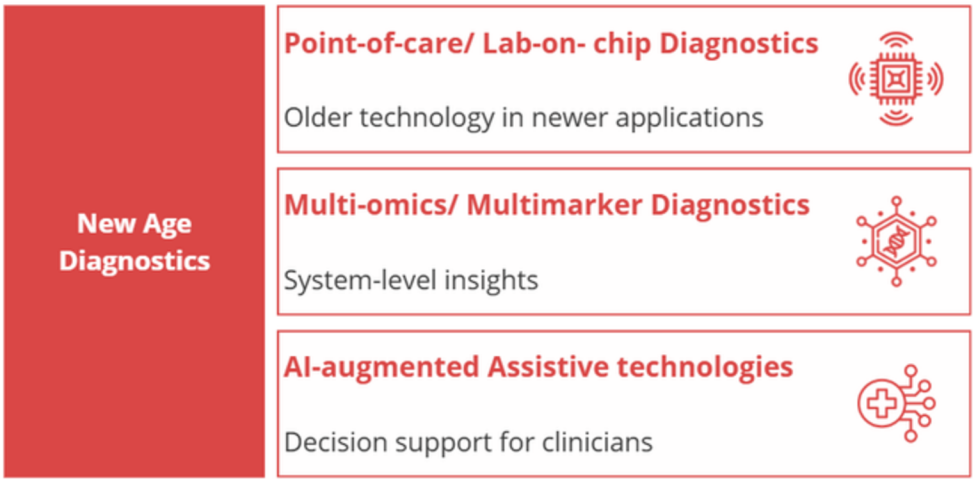

Fig 1. The New Age Dx Categories

Point-of-Care / Lab-on-Chip Systems

Point-of-care chip systems miniaturise laboratory workflows onto compact, low-cost platforms that can be deployed at the bedside, clinic, or community level. By integrating microfluidics, sensors, and embedded processing, these systems reduce reliance on central labs while maintaining acceptable clinical performance.

The technology itself is not new, however the applications have truly begun to come onto their own only in the past few years with COVID as a major tipping point. The main value of point-of-care systems lies in **infrastructure substitution**. Chip-based diagnostics trade expensive logistics, skilled manpower, and turnaround delays for immediacy and reach - enabling earlier diagnosis, faster triage, and better programme coverage. For policymakers, this creates opportunities for decentralised screening and task-shifting. For investors, it opens scalable hardware-plus-consumables models anchored in.

Multi-omics / Multi-marker Diagnostics

Multi-omics diagnostics combine signals across genomics, proteomics, metabolomics, and related systems biological layers to generate richer, more contextual insights from a single

sample. Rather than answering binary questions ("positive or negative"), these approaches characterise disease risk, progression, and response with greater precision.

Multi-omics represents **signal densification**. By extracting multiple clinically relevant insights from one test event, these platforms improve cost-effectiveness even when per-test prices are higher. Their strategic value lies in population stratification, preventive care, and chronic disease management, making them especially relevant for insurers, public health programmes, and outcome-linked care models. However, cost remains a constraint in the Indian context, but recent progress means that it is within reach.

AI-Augmented Interpretation & Assistive Technologies

AI-augmented assistive diagnostics use algorithms to interpret images, waveforms, and complex biological data - supporting clinicians rather than replacing them. These systems improve consistency, reduce diagnostic variability, and extend specialist expertise into resource-constrained settings.

For India, their core contribution is **workforce amplification**. By embedding clinical intelligence into devices and workflows, AI assistive tools increase throughput and quality without proportionally increasing human capacity. For policymakers, this enables scale within existing staffing constraints. For investors, it positions diagnostics as software-enabled platforms with defensible data moats, recurring revenues, and downstream integration into care pathways.

Dimension	Point-of-Care Chip Systems	Multi-Omics Diagnostics	AI-Augmented Assistive Tech
Core system problem addressed	Infrastructure substitution	Signal Densification	Workforce amplification
Primary value to policy-makers	Decentralised access, faster triage, programme scale	Better targeting of interventions, preventive care	Standardisation, task-shifting, scale without hiring
Primary value to investors	Scalable hardware + consumables, volume-driven demand	High-value insights, payer & insurer relevance	Software leverage, data moats, recurring revenue
Best-fit care settings	Primary care, community screening, outreach	Tertiary care, chronic disease programmes, cohorts	Primary–secondary continuum
Cost logic	Lower cost via logistics and labour reduction	Higher unit cost, lower cost per insight	Marginal cost near zero after deployment
"More biology per rupee" pathway	Faster, closer, more frequent testing	More insight from fewer tests	More decisions from the same workforce

Fig 2. Ecosystem overview of new-age diagnostics

1.The Decade of Change for IVDs

1.1 Technology advances

1.1.1 Microfluidics and Lab-on-Chip Technologies

Microfluidic platforms have fundamentally transformed point-of-care diagnostics by integrating sample preparation, analytical processing, and detection mechanisms within single-device architectures. While microfluidics itself is a well-established technology, COVID has given it a boost. Digital microfluidics has emerged as a critical enabler for automated fluid handling in nucleic acid amplification tests (NAAT), with substrate materials spanning paper-based matrices for resource-limited settings to precision-engineered PDMS and glass constructs.

1.1.2 Optical and Photonic Detection Systems

Silicon photonics biosensors exploit high refractive index contrast to achieve compact, label-free detection capabilities with enhanced sensitivity. Complementary metal-oxide-semiconductor (CMOS) sensor technology has achieved performance parity with charge-coupled device (CCD) systems at substantially reduced cost points, while mid-infrared spectroscopy has enabled non-invasive breath biomarker analysis for clinical applications.

1.1.3 Electrochemical Biosensors and Portable Molecular Platforms

Portable electrochemical biosensors demonstrate high analytical sensitivity for biomarker quantification across diverse biological matrices. Loop-mediated isothermal amplification (LAMP) technology facilitates nucleic acid amplification at constant temperatures (60–65°C), achieving detection limits of fewer than 10 copies, with deployment increasingly enabled through smartphone-integrated diagnostic systems.

1.2 Economies of Scale

1.2.1 Manufacturing Capacity Expansion During the COVID-19 Pandemic

The global health emergency precipitated a 200% expansion in rapid diagnostic test (RDT) manufacturing capacity - from 482 million tests per month in October 2020 to 1 billion tests per month by April 2021 - accompanied by a 30% reduction in average unit pricing. Within India, indigenous RT-PCR kit costs declined from $70 to below $10, while initiatives such as the Indigenisation of Diagnostics (InDx) program enabled over 150 small and medium enterprises to achieve collective production capacity exceeding 1 million test kits daily.

1.2.2 Standardised Reagent Production and Laboratory Information Management Systems

Good Manufacturing Practice (GMP)-compliant production processes ensure batch-to-batch consistency for critical raw materials, including enzymes, monoclonal antibodies, and chemical stabilisers. Contemporary Laboratory Information Management Systems (LIMS) facilitate real-time sample tracking, workflow automation, and regulatory compliance across high-throughput diagnostic environments.

1.3 Algorithmic and Computational Layer

1.3.1 Computer Vision and Artificial Intelligence in Pathology

Advances in artificial intelligence and machine learning have resulted in artificial models nearing human-level accuracy for image analysis, and in some cases identifying patterns that are not always obvious to humans, Foundation models trained on datasets comprising over 1.5 million whole-slide images have demonstrated physician-level diagnostic accuracy, with regulatory approval of artificial intelligence-enabled pathology systems by the United States Food and Drug Administration commencing in 2021.

1.3.2 Machine Learning-Driven Biomarker Discovery

Machine learning methodologies enable integration of multi-omics datasets - encompassing genomics, proteomics, and metabolomics - for identification of diagnostic and prognostic biomarkers, with demonstrated superiority over conventional polygenic risk scores across more than 3,000 disease conditions.

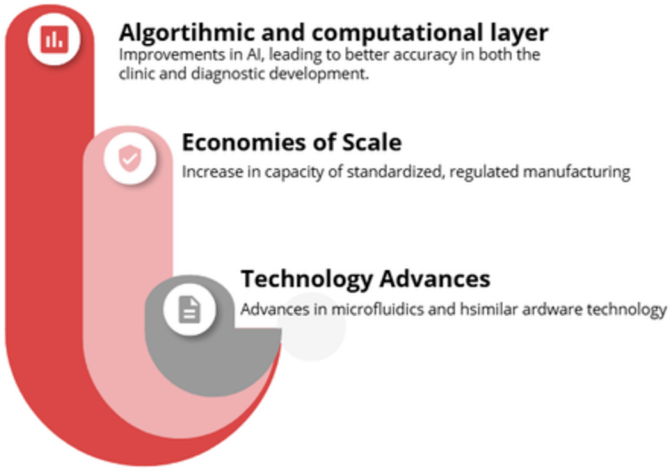

Fig 3. Drivers for IVD advancements

1.3.3 Multianalyte Algorithmic Interpretation

Multianalyte assays with algorithmic analyses (MAAAs) combine two or more biomarkers with patient demographic parameters to generate composite diagnostic scores. Although not specifically artificial intelligence, MAAAs have several recent established examples, including the 4Kscore, OVERA, and PreDx Diabetes Risk Score, the latter incorporating seven biomarkers with a reported area under the curve (AUC) of 0.84.

2.India’s IVD Moment is now

Today, India is well-poised to become a leader in innovative in-vitro diagnostics, on the back of some strong tailwinds and large market opportunities.

2.1 Cost-Sensitive, High-Volume Market

India's diagnostics landscape combines enormous scale with intense price sensitivity. Out-of-pocket payments still constitute approximately 47% of total health expenditure, making affordability paramount. The diagnostic laboratories market, valued at INR 1.54 trillion in FY2024, is projected to reach INR 2.98 trillion by FY2030 (~11.7% CAGR).

Growth is driven primarily by volume expansion rather than pricing gains. Major diagnostic chains report sample volume growth of approximately 9–10% annually, while per-test pricing remains flat or grows only marginally.This "volume over price" model has enabled organized players such as Dr. Lal PathLabs and Metropolis Healthcare to sustain EBITDA margins of 27–28%, leveraging economies of scale from high-throughput lab infrastructure.

Despite millions of tests performed annually, India remains underpenetrated relative to its population. Urban metros demonstrate significantly higher test utilization (1,500–2,000 tests per 1,000 population) compared to non-metro areas (550–600 per 1,000). Government programs such as Ayushman Bharat and private hub-and-spoke collection networks are expanding access into underserved areas. A high-volume, low-cost strategy remains essential for success in this market.

2.2 Shortage of Pathologists

India faces a chronic shortage of qualified pathologists. The global mean stands at approximately 14 pathologists per million population, with North America at 50–65 per million and Europe at 26 per million. Asia averages only 6.8 per million, while India is estimated at approximately 4 to 5 per million - a severe deficit that means one pathologist often serves tens of thousands of patients.

The shortage is most acute outside major cities. Most NABL-accredited laboratories (~2,500+) are concentrated in urban centres, while rural facilities often operate without certified pathologists. The Clinical Establishments (Registration & Regulation) Act, 2010 mandates that laboratories employ qualified personnel, though implementation remains uneven - 19 States and Union Territories have adopted the Act as of 2024.

This workforce gap is driving innovation in digital pathology and AI-assisted diagnostics. Companies such as 4basecare are using AI for multi-omic cancer detection. Telepathology (and tele-radiology) services allow specialists in metropolitan hubs to review digitized samples from remote clinics, optimizing scarce expertise. For investors and healthcare providers, the pathologist shortage signals a significant market opportunity for solutions that mitigate human resource constraints - including training programs, lab automation, and AI-driven diagnostics.

2.3 Strong AI and hardware talent pool

India's diagnostic industry can leverage its deep engineering and IT talent base. The nation's AI workforce reached 416,000 professionals by 2025, though a 51% demand-supply gap persists. This talent pool supports development of AI-driven diagnostic solutions - the India AI in medical diagnostics market is expanding rapidly, projected to grow at approximately 23% CAGR through 2030.

Hardware and manufacturing capabilities are strengthening through government initiatives. The medical devices sector, valued at approximately $12 billion in FY2023–24, is projected to reach $50 billion by 2030.1920 The Production-Linked Incentive (PLI) scheme has allocated INR 3,420 crore (~$400 million) for domestic manufacturing, with 22 greenfield projects commissioned by September 2025. Medical device exports grew from USD 2.5 billion in FY21 to USD 4.1 billion in FY25, demonstrating improving competitiveness.

2.4 Growing regulatory maturity

IIVDs (and the healthcare sector as a whole) is transitioning from fragmented regulation toward structured oversight. The Central Drugs Standard Control Organization (CDSCO) has brought in-vitro diagnostics (IVDs) under the Medical Device Rules, 2017, classifying devices by risk level: Class A (low risk), Class B (low-moderate), Class C (moderate-high), and Class D (high risk). All Class C and D IVDs - including tests for infectious diseases, blood screening, and cancer markers - now require rigorous premarket review and Central Licensing Authority approval.

The Ayushman Bharat Digital Mission (ABDM) creates a unified health data ecosystem with Health IDs and longitudinal patient records. Diagnostic laboratories are integral to this system, with digital lab reports feeding into Health IDs to enable better care continuity and support algorithmic decision-making.The Digital Personal Data Protection Act, 2023 establishes privacy safeguards for sensitive health data, with penalties reaching up to ₹250 crore for serious violations.

These shifts - formal IVD regulation, digital infrastructure, and data protection - create a level playing field for compliant players. Enterprises that invest in quality systems, cybersecurity, and regulatory-grade validation will gain a distinct advantage as India's diagnostic market evolves toward a structured, technology-forward industry.

2.5 Need for preventive healthcare

Part of a global trend, India is also experiencing an urgent shift toward preventive healthcare, driven by a rising burden of chronic diseases. Non-communicable diseases (NCDs) now account for approximately 63–65% of all deaths in India, increasing from 37.9% in 1990 to 61.8% by 2016. A 2022 Lancet study reported that India accounts for 212 million of the world's 828 million diabetics - over 25% of the global burden - with approximately 62% remaining untreated.

Government programs are scaling preventive screening. Under Ayushman Bharat, over 178,000 Ayushman Arogya Mandirs (formerly Health and Wellness Centres) now provide community-level screening. By July 2024, these facilities had conducted over 84 crore (842 million) hypertension screenings and 74 crore (741 million) diabetes screenings, with total footfall exceeding 317 crore visits. Meanwhile, hypertensive heart disease deaths increased 138% between 1990 and 2013, underscoring the need for proactive intervention.

The preventive healthcare sector - encompassing fitness, wellness, early diagnostics, and health tracking - is projected to reach $197 billion by 2025, growing at 22% CAGR. Over 40 preventive healthtech startups have raised approximately $1 billion in funding over three years.The health check-up market specifically reached $1.7 billion in 2024, with projections of 6.8–11% CAGR through 2030–2033 This trajectory reflects intensifying consumer awareness and corporate wellness adoption, positioning preventive diagnostics as a major growth vector.

2.6 Linking IVD to insurance

India's health insurance penetration remains strikingly low—approximately 37–41% of the population has some form of coverage, while nearly 900 million Indians remain uninsured. This gap presents a strategic opportunity for IVD-driven interventions to simultaneously expand insurance uptake and reduce systemic healthcare costs.

There is strong evidence that using diagnostic data for risk assessment and underwriting, using baseline health metrics help insurers to price policies accurately and identify high-risk individuals for targeted interventions. The first change here is in wellness programs offered by insurers now routinely include incentives for preventive health check-ups—premium discounts, reward points, and free annual screenings.

The economic rationale is compelling: early-stage diagnosis through IVD can reduce treatment costs by 5–10x compared to late-stage intervention, as evidenced by US data showing cancer screening programs saved $6.5 trillion over 25 years. For chronic diseases like diabetes and cardiovascular condition - which account for 63% of deaths in India—predictive diagnostics enable proactive management, reducing hospitalization frequency and claim severity. Under Ayushman Bharat, expanding coverage to include standalone preventive diagnostics- particularly for NCDs - could drive both insurance penetration and population health outcomes. As India's IVD ecosystem matures with CDSCO regulation and digital integration under ABDM, insurers gain access to validated, interoperable diagnostic data that supports precision underwriting and population health management. This convergence of diagnostics and insurance represents a critical lever for transitioning India from a reactive, high-cost treatment model to a preventive, sustainable healthcare system.

The Cost of Inaction: A CKD Case Study

Chronic Kidney Disease (CKD) affects an estimated 15–16% of India's adult population, yet approximately 90% of patients remain undiagnosed until they reach Stage 4 or 5, when life-sustaining dialysis becomes unavoidable. Under the Pradhan Mantri National Dialysis Programme (PMNDP), the public cost of maintaining a single End-stage Renal Disease (ESRD) patient is approximately **₹2.0 lakhs per year**, with private dialysis running ₹24,000–50,000 per month.

A modelled **"Screen-to-Manage" i**ntervention targeting 100 million high-risk adults (diabetics and hypertensives) demonstrates a compelling alternative. IVD-based screening costs just **₹150–400 per person annually,** while early-stage management adds ₹3,000–15,000 per patient per year — a fraction of downstream dialysis expenditure. Over a 10-year horizon, this approach could avert 3.2 million ESRD cases, generating cumulative public savings of ₹64,000 crore against an annual programme investment of ₹28,000 crore. The model achieves fiscal break-even by Year 6–7, with a Benefit-Cost Ratio of 2.28:1. Real-world validation from the Telangana pilot (2025) reinforces these projections: a ₹60 crore screening investment averted an estimated ₹1,100 crore in dialysis costs.

₹2 Lakh	3.2 M	₹64,000 CR	2.28:1
Annual public cost for 1 ESRD patient	**Est. lives saved with early detection**	**Est. annual cumulative public savings**	**Benefit cost-ratio**

Full analysis in the appendix

3.Leveraging IVDs for India's health system

With the case for IVDs established, we now examine how we can leverage new-age diagnostics to leapfrog India's heathcare system into the next stage.

3.1 Implement Early Detection Programs for Proactive Care

Diagnostics enable diseases to be caught at initial stages when intervention is most effective. **A small investment in timely tests yields disproportionate gains in health outcomes,** as appropriate early testing allows earlier treatment and averts expensive late-stage care. For example, screening programs for cancers or chronic conditions can preserve years of healthy life for minimal test costs. One analysis noted that each additional tuberculosis case detected through active diagnostic outreach averts roughly one disability-adjusted life year (DALY) of disease burden – a striking return in health for the cost of a test. In short, IVDs provide more actionable "signal" per rupee by catching diseases before they escalate, improving survival and quality of life.

3.2 Enable Risk Stratification and Targeted Treatment

Beyond diagnosis, IVDs stratify patients by risk (e.g. genetic markers, cholesterol or troponin levels), guiding preventive measures to those who need them most. This *yield-enhancing* approach means limited resources can be focused on high-risk patients identified by affordable tests, maximizing the health benefit per test. **High-quality diagnostics directly influence treatment decisions and outcomes** – for instance, a simple blood test can now determine whether a cancer patient needs aggressive therapy or can be managed conservatively, thus extracting more clinical insight per rupee. By delivering medically relevant information that guides decision-making, modern IVDs ensure that each test result leads to tangible patient benefits.

3.3 Utilize Multiplexed and High-Actionability Tests

Advances in IVD technology now allow multiple biomarkers to be assessed in one go, extracting far more biology from a single patient sample. These multiplex or panel tests increase the probability of catching diseases early and provide a comprehensive picture of patient health in one affordable procedure. The result is more relevant data per rupee: instead of separate, fragmented tests, one broad assay can reveal a spectrum of issues (e.g. simultaneous screening for several infections or a whole panel of metabolic markers) at little

added cost. **Such broader diagnostic "signal" for each test dollar leads to earlier interventions and better outcomes,** as evidenced by improved survival rates when conditions like cancers, HIV, or diabetes are detected through proactive lab screening rather than late-stage symptoms. In sum, IVDs boost the clinical yield – more health information and earlier lifesaving action per rupee – making diagnostics indispensable for efficient, high-impact care

3.4 Get More Insight per Spend and High ROI on Diagnostics

In-vitro tests typically consume only ~2% of healthcare spending, but remarkably inform ~70% of all clinical decision-making. This imbalance highlights how each rupee spent on diagnostics leverages many rupees' worth of treatment value – an enormous return in informational yield. By guiding physicians on when to intervene, what therapy to choose, or when to avoid unnecessary procedures, IVDs ensure that small diagnostic costs unlock much larger cost-effective outcomes. **The ability to pinpoint the right care (or avoid wasteful care) means more insight per spend:** every rupee invested in testing drives better use of the much larger treatment budget, exemplifying "more biology per rupee" in financial terms.

Further, studies consistently show high returns on investment (ROI) for diagnostic programs. A recent 1**0-year analysis of South Africa's public molecular testing program (for HIV, TB and COVID) found an average ROI of ~13.9** – meaning each $1 spent yielded about $14 in economic benefits from improved health. Specific tests had striking returns (e.g. **TB diagnostics ROI ~20; early infant HIV tests ROI ~63**). Such returns rival or exceed those of classic public health interventions like childhood vaccinations, underscoring diagnostics as a high-value investment, not a cost sink. Notably, deploying diagnostics in decentralized community settings was far more cost-efficient than hospital-based testing (shifting tests to hospitals cut net benefits by 40–50%) – evidence that IVDs deliver more insight per rupee when brought closer to patients, avoiding infrastructure overheads. In short, whether through preventing expensive late-stage treatments or enabling more efficient care pathways, diagnostics often pay for themselves many times over.

3.5 Maximize Macro-Level Savings & Boost Decentralization

At the health system level, spending on diagnostics can reduce overall costs by enabling prevention and appropriate care. India's public initiatives illustrate this: the Free Diagnostics Service Initiative under the National Health Mission, which provides essential tests at no cost, aims to lower out-of-pocket expenditures and avoid downstream expenses. In Andhra Pradesh, for example, **providing free lab tests led to an estimated ₹228 crore (≈US$35 million) in patient cost savings in just 18 months.**

These savings represent money not spent on unmanaged disease complications or unnecessary referrals due to lack of test access. Furthermore, IVDs support cost-effective decentralization – equipping primary health centers and even homes with affordable tests (e.g. point-of-care kits for blood sugar, pregnancy, or COVID-19) reduces costly hospital visits and travel. By bringing diagnosis closer to the patient, the system squeezes more health value out of each rupee, as the same tests done early in the community avert significantly higher expenditures on advanced disease in tertiary care. For policymakers and investors, the message is clear: diagnostics are not a cost center but a high-yield asset that increases the efficiency of health spending.

3.6 Maximize Output of Labs and Workforce

A robust diagnostics network allows a given infrastructure to serve a far larger population with accurate care. For example, South Africa's National Health Laboratory Service (NHLS) – through centralized labs and daily sample transport – **performs around 107 million tests per year, supporting ~85% of the country's population.** This shows how one well-organized lab system can multiply coverage and relieve frontline facilities. In India, too, strengthening diagnostic labs is seen as pivotal to healthcare delivery; labs provide the data for diagnosis, treatment planning, and disease monitoring that make all other health services effective. Modern IVD automation and networking mean that **one laboratory or device can handle volumes that would have required many more staff or centers in the past,** alleviating shortages of specialists. For instance, automated analyzers and point-of-care devices enable basic health units to perform tests without a full laboratory infrastructure, effectively increasing the health output per clinic or per worker. By minimizing manual bottlenecks and errors, and freeing skilled personnel from repetitive tasks, diagnostic automation greatly enhances throughput and reliability. In essence, IVDs let a limited health workforce do far more with the same infrastructure, amplifying the system's overall capacity.

3.7 Reduce Reliance On Tertiary Infrastructure

IVDs drive a shift from high-cost hospital-centric care to distributed models. When accurate tests are available in primary care or community settings, many conditions can be detected and managed early without burdening tertiary hospitals. **This decongests infrastructure and multiplies the value of each healthcare facility.** For example, widespread availability of rapid diagnostic kits (for malaria, COVID-19, etc.) and basic lab tests in rural clinics means that patients receive timely care locally, and referrals to hospitals are reserved for truly complex cases. The result is better utilization of expensive hospital beds and specialists – a systemic efficiency gain. The Government of India's Essential Diagnostics List (2019) and Free

Diagnostics Initiative explicitly aim to homogenize test availability at every level of care, so that **a village clinic can perform the key tests to manage most common conditions.** This not only improves equity but also ensures that large hospitals are not overwhelmed with cases that could have been handled with a rupee's worth of testing at the periphery. In short, diagnostics multiply "yield per infrastructure" by allowing lower-level facilities to effectively address health issues, thereby leveraging the entire network more efficiently.

3.8 Utilize ABDM for Digital Integration and Data Leverage

Perhaps the most powerful system-level boost comes from digital integration of diagnostics. When each test's result is digitized and connected, its value is amplified across the healthcare ecosystem. India's Ayushman Bharat Digital Mission (ABDM) is spearheading such integration – linking labs, electronic health records, and providers on a unified platform. For instance, a lab result uploaded to a patient's digital health ID can be instantly accessed by doctors anywhere, enabling remote consultations and eliminating duplicate testing. **Telemedicine combined with reliable IVD results allows a single specialist to guide care for patients in multiple distant clinics, effectively multiplying expert reach.** Moreover, aggregated diagnostic data feeds into public health surveillance and planning (e.g. spotting outbreaks or disease trends in real time), extending the impact of each test beyond the individual patient. **The ABDM-driven digital connectivity will increase accuracy, reducing errors, and cutting delays in lab services by streamlining how results are managed and shared.** For example, laboratory information management systems (LIMS) under ABDM ensure that diagnostic information is available quickly and accurately to all care providers, improving coordination and outcomes. Such integration means every rupee spent on a test yields not just a one-time result, but a piece of data that can inform multiple decisions and even policy. The system-level payoff is immense: improved care coordination, lower administrative overhead, and better allocation of resources based on real-time diagnostic insights.

3.9 Overall Systemic Resilience and Quality Gains

A diagnostics-rich system is more resilient and quality-driven. During health crises like the COVID-19 pandemic, countries with decentralized testing and robust lab networks managed better testing coverage and data-guided responses. Generally, **investing in diagnostics is now recognized as essential to health system strengthening** – lack of diagnostics is deemed a major obstacle to improving healthcare outcomes. Without tests, providers resort to blind trial-and-error treatments, which can waste resources and even fuel problems like antimicrobial resistance. Conversely, a system flush with accurate IVD capabilities ensures that treatments and interventions are guided by biological evidence ("more biology per rupee" guiding each decision), leading to better overall efficiency and safety. In India, the

creation of the National Essential Diagnostics List and dedicated diagnostic funding is a step in the right direction that reflects this understanding that diagnostics are as indispensable as medicines for a high-performing health system. **By embedding quality diagnostics at all levels, the healthcare system can do more with the infrastructure it has – each health center becomes more capable, each healthcare rupee more impactful.**

> In conclusion, in-vitro diagnostics exemplify the "more biology per rupee" principle across clinical, economic, and system domains. They deliver outsized clinical benefits by catching diseases early and tailoring care (maximizing health yield per test). They offer exceptional economic value and ROI by informing efficient spending and preventing costly outcomes (more insight per healthcare dollar). They also strengthen health systems by multiplying the reach and productivity of infrastructure and workforce, especially when bolstered by digital integration. For policymakers and investors, the evidence is compelling: **diagnostic tools are high-yield investments that amplify the effectiveness of every other health expenditure.** Far from being just ancillary costs, IVDs are strategic enablers that extract maximum biological information and value from each rupee, driving better outcomes and sustainable healthcare growth.

4.Current challenges for the IVD ecosystem

Despite well-established evidence that shows the importance and need for in-vitro diagnostics, there is still a significant gap in implementation. This gap is apparent not just in India, but globally.

4.1 Infrastructure Hurdles

New point-of-care (PoC) “lab-on-chip” systems, multi-omics assays, and AI-driven diagnostic tools promise more information per rupee, but they often struggle to match the reliability of established lab tests at competitive costs. Early generations of PoC devices, while portable and quick, have faced issues like lower sensitivity or more user-dependent errors than central lab diagnostics. **In practice, factors such as non-ideal environmental conditions or operator training can compromise PoC accuracy, eroding clinician confidence.** Achieving lab-grade precision typically raises costs due to added quality controls and better materials, challenging affordability in resource-limited settings. Multi-omics diagnostics (integrating genomics, proteomics, etc.) face a different infrastructure hurdle: they require advanced lab equipment and bioinformatics support, historically making them expensive niche offerings. Upfront costs for comprehensive multi-omic testing have been significantly higher than standard single-analyte tests, limiting widespread use. AI-augmented diagnostic tools, meanwhile, must prove themselves against incumbent methods. Some AI systems have equaled or even exceeded physician accuracy in controlled studies, **but concerns about bias and reproducibility mean they require extensive validation before trust and regulatory approval.** These technology infrastructure gaps – needing stable power, connectivity, high-end hardware, or large datasets – further constrain deployment in many clinics and rural areas.

Encouragingly, innovators are closing the gap on both accuracy and cost. For example, India’s Truenat – a chip-based, battery-operated molecular test – achieved accuracy on par with the gold-standard GeneXpert lab platform for tuberculosis, at lower cost and with minimal lab infrastructure. Its WHO endorsement and rollout demonstrate that point-of-care tools can meet stringent standards. Likewise, the cost of genomics is plummeting: as of 2024, high-throughput sequencers can decode a human genome for around $200, with $100 genomes on the horizon. These trends suggest new IVD technologies can deliver “more biology per rupee” as engineering refinements and economies of scale improve accuracy and affordability in tandem.

4.2 Cost Structure & Incumbent Incentive Challenges

Even when novel diagnostics prove their technical merit, scaling them into routine use presents economic and incentive barriers. Many disruptive IVD platforms have a fundamentally different cost structure than incumbent diagnostics. For instance, a point-of-care analyzer might require upfront device purchases and pricier per-test cartridges – costs that small clinics or labs hesitate to bear without clear reimbursement. Indeed, **high operating expenses (instruments, maintenance, and training) and limited insurance coverage have historically deterred providers from adopting on-site tests** that could be done more cheaply at large labs. Incumbent industry players (e.g. big reference laboratories and diagnostic firms) also lack incentive to promote innovations that might undercut their existing services. They tend to stick to high-volume tests with established codes and workflows, rather than integrate a radically new multi-omics platform or AI decision-support tool that doesn't fit neatly into the billing and workflow model. This status quo bias means promising diagnostics often face a "valley of death" in scaling - i**ncumbents focus on incremental improvements and have little extrinsic motivation to invest in disruptive platforms that could reset cost structures.**

There are signs however this dynamic is changing. **The COVID-19 pandemic forced healthcare systems to rapidly deploy new diagnostics (from at-home rapid antigen kits to portable PCR devices), showing that adoption can accelerate when the value is undeniable**. In some cases, incumbent companies have begun partnering with or acquiring innovators, integrating new tech into their offerings. Notably, large IVD players and labs signaled renewed interest in 2025 to invest in diagnostics that complement their core business. Recent acquisitions underscore this trend – for example, Thermo Fisher's multi-billion-dollar purchase of Olink's proteomics platform indicates incumbents seeking to own next-generation tools rather than resist them. Additionally, government and non-profit interventions are helping overcome scale barriers. In India, the public health system endorsed and deployed Truenat nationwide to replace outdated smear microscopy, effectively pulling a disruptive innovation into scale through policy support. Such moves – alongside new reimbursement models and consortiums to evaluate emerging tests – suggest that with the right incentives realigned, novel IVDs can achieve scale and start delivering far more "biology per rupee" than the status quo.

4.3 Venture Funding and Exit Constraints

The diagnostics sector has long been viewed by investors as a slower, less lucrative arena compared to therapeutics. Historically, only a small fraction of healthcare R&D investment (around ~3%) has gone toward diagnostics tools. This chronic under-funding stems from structural factors: diagnostic tests are typically seen as targeting smaller markets and yield-

-ing lower margins than blockbuster drugs, offering little prospect of the outsized "homerun" returns venture capitalists crave. **The result is a capital crunch that limits new IVD development and commercialization.** Startups in diagnostics often struggle to raise growth capital or achieve exits through IPOs; most successful outcomes have been strategic acquisitions by larger companies. In recent years, even as biotech funding boomed, diagnostics funding lagged – and in 2023 it plunged further by 37%, reflecting investor caution in a segment perceived as capital-intensive and slow to pay back. Building multi-omics or AI diagnostic platforms requires substantial upfront investment (for technology development, clinical validation, regulatory approval) before revenue flows, testing the patience of traditional VC timelines. Additionally, uncertain reimbursement and regulatory paths for advanced diagnostics have made investors wary, especially after some high-profile diagnostics failures in the past.

Despite these headwinds, there are promising signs that the "tide is turning" for diagnostics investment. **The COVID-19 experience underscored the critical value of diagnostics in healthcare, prompting large-scale initiatives like the NIH's $1.5B RADx program to fund innovative testing technologies.** This infusion of non-dilutive capital and public attention has validated the space. We are also seeing a new generation of diagnostics companies achieving significant valuations and exits, suggesting growing investor confidence. For example, India's Molbio Diagnostics – maker of the Truenat platform – secured major private funding and reached unicorn status with a $1.6 billion valuation in 2022, a remarkable milestone for an IVD-focused firm. Global M&A activity is likewise picking up: major life-sciences players have acquired niche diagnostics innovators (e.g. Thermo Fisher acquiring Olink for $3.1B, Danaher buying antibody specialist Abcam for $5.7B) to bolster their portfolios. These exits provide workable models and returns that can attract more venture capital into the field. Additionally, specialized funds and public-private partnerships (such as India's Biotechnology Industry Research Assistance Council co-funding diagnostics startups) are de-risking early development. While diagnostics still represent a smaller slice of healthcare VC, the convergence of multi-omics, AI, and a push for personalized medicine is making diagnostics more central to future healthcare – and investors and policy-makers alike need to recognize that funding this segment can yield both significant health impact and sustainable financial returns.

4.4 Clinician Adoption: Workflow Integration & Skepticism

Even when new diagnostics are made vailable, clinician acceptance remains a pivotal hurdle. Busy healthcare providers often resist tools that disrupt clinical workflows or add uncertainty. In many cases, novel point-of-care tests and AI decision aids have been seen as additional burdens rather than boons, especially if they operate outside of existing IT systems. **Clinicians already stretched thin have been reluctant to adopt new IVD tools**

that do not integrate seamlessly with their routine – no matter how impressive the technology – resulting in slower-than-expected uptake for even well-validated innovations. Lack of integration with electronic health records and lab reporting means results from a point-of-care device or AI app may not flow into the patient's chart, creating extra steps and potential errors. Moreover, skepticism about diagnostic accuracy and clinical utility remains: doctors trust what they know. If a multi-omics test yields a complex genomic risk profile, a general physician may be unsure how to act on it during a 15-minute consult. Similarly, "black box" AI algorithms that lack explainability can raise understandable concern – physicians are hesitant to rely on an aid they don't fully understand, especially when liability for decisions still falls on them. Cultural resistance ("we've always managed without this tool") and limited awareness or training on new devices contribute to slow adoption. These factors blunt the impact of innovations that could potentially provide far richer patient data per rupee spent, if utilized fully.

Efforts are underway globally and in India to bridge the gap between innovation and clinical practice. **A key focus is embedding new diagnostics into existing workflows so they assist rather than obstruct.** For example, in radiology and pathology AI, developers now integrate AI outputs directly into PACS/EHR systems, presenting results in familiar formats to ease clinician use. Training and demonstration projects have shown that when clinicians see clear benefits – like time saved or diagnoses they might have missed – attitudes shift. In India's public health sphere, successful pilots have improved confidence: Tamil Nadu's state TB program recently incorporated an AI tool for chest X-ray screening in mobile clinics, which greatly expanded screening and identified cases earlier without overburdening doctors. The AI was used as an assistive triage, and ultimately 92% of the TB cases that were diagnosed had been flagged by the AI – giving clinicians tangible evidence of its value. Globally, regulatory bodies and professional associations are developing guidelines for AI and multi-omics use, helping legitimize these tools. Notably, experts suggest holding AI diagnostics to the same standards as human experts, requiring that they meet or exceed median physician performance before deployment. As more trials demonstrate that new IVD tools can improve outcomes and reduce workload, early adopter clinicians are becoming champions of these technologies. In sum, by improving usability and trust – through better integration, education, and evidence – the healthcare system will gradually overcome skepticism. This shift bodes well for the future, where clinicians embrace AI-augmented and multi-omic diagnostics to deliver more precise, efficient care, truly getting more biological insight for every rupee spent on testing.

5.Benchmarking global systems

For the purposes of this white paper, we chose to evaluate and bechmark four other health systems from an IVD lens - the US, Ireland, Switzerland and China. These countries were selected based on a combination of health system, government policy, manufacturing capability and emphasis on innovation.

5.1 The United States

The US has by far the largest IVD market, accounting for roughly 40% of global revenues. Its ecosystem is rich in innovation: hundreds of companies (from giants like Roche, Abbott, Thermo Fisher to numerous startups) develop immunoassays, molecular platforms (PCR and NGS), and emerging AI-driven tools (e.g. digital pathology). Point-of-care testing is widespread (many CLIA-waived rapid tests and portable analyzers), and R&D in AI/ML diagnostics is advancing rapidly. In 2024 the US IVD market was ≈$41.4 billion and projected to grow ~5–6% annually. Growth has been driven by an aging population, rising chronic disease, and biomedical R&D investment. Government and NGO funding (NIH, DARPA, CARB-X, etc.) supports new diagnostics – for example, NIH granted $78 M in 2021 to develop rapid infectious-disease tests. The FDA regulates IVDs through 510(k)/PMA pathways, CLIA-waivers for POC tests, and has recently begun adapting its framework for AI/ML components. Robust IP protection and public–private partnerships further bolster the US IVD sector.

The US ecosystem combines strong public research funding, a flexible regulatory framework (including emergency EUAs during COVID-19), and ample private capital. Immunoassays dominate (65.9% of US IVD market in 2024) but point-of-care nucleic-acid tests (e.g. Cepheid GeneXpert, Roche cobas) and AI-enhanced IVDs are rapidly expanding. Continuous NIH grants and R&D tax credits incentivize innovation while initatives such as NIH/NIBIB Point-of-Care Technologies Research Network (POCTRN, created 2007) promotes academic–industry collaborations for POC tests.

5.2 Ireland

Ireland's IVD industry is intertwined with its broader medtech sector, which employs ~63,000 people across 300+ companies. Attractive fiscal policies – a low corporate tax rate (12.5%) and generous R&D tax credits – have drawn almost all top global medical-device firms to establish R&D and manufacturing sites in Ireland. Consequently, medtech exports

exceed €13 billion annually (≈8% of Irish exports). Dublin, Galway, and Cork host clusters of companies producing diagnostics reagents and devices. Ireland's EU membership provides seamless access to European markets, and the national regulator (HPRA) enforces EU IVDR standards.

Over the past 25 years Ireland has built a strong life-sciences cluster via foreign direct investment. Policy drivers include low tax rates, 25–30% R&D credits, and government agencies (IDA Ireland, Enterprise Ireland) that actively support life-sciences projects. Many IVD products (especially immunodiagnostic kits and blood analyzers) are manufactured there. Ireland's regulatory processes (CE marking under IVDR) are aligned with Europe, which aids exporters. The skilled workforce and favorable business climate continue to fuel gradual expansion of diagnostics R&D and production.

5.3 Switzerland

Switzerland is a global hub for diagnostics R&D. It is home to Roche Diagnostics (Basel), the world's largest IVD company (CHF 14.1 billion in sales in 2023), as well as numerous specialized medtech firms. In total, Swiss medtech generated ~CHF 17.9 billion in revenue (2020) with 1,400 companies and 63,000 employees. The country consistently ranks first on innovation indices and invests heavily in healthcare technology. Its ecosystem features top universities (ETH Zurich, Univ. of Basel) and a national network of innovation parks that foster collaboration between academia and industry.

Switzerland's policies strongly support high-tech life sciences. For example, startups can receive corporate-tax breaks (up to 10 years) and public grants, and venture funding for medtech has grown ~51% from 2012–2021. Over 90% of Swiss device makers collaborate with research institutes. Swissmedic (the national regulator) maintains strict standards but recognizes CE markings via bilateral agreements. As a result, Swiss-based diagnostics (from immunoassays to molecular analyzers) lead in quality. The confluence of R&D incentives, strong IP protection, and a highly skilled talent pool has kept Switzerland's IVD sector robust.

5.4 China

China's IVD industry has transformed dramatically since the 1980s. Once relying entirely on imports, it is now the world's second-largest IVD market and production base. The market reached ~¥800 billion (≈$110 billion) by 2018 and has continued growing (8–10% annually). Traditional immunodiagnostics dominate demand, but molecular diagnostics (PCR, NGS) and point-of-care tests (POCT) are the fastest-growing segments (often >20% annual growth). Government policy has been a key driver: initiatives like "Healthy China" and "Made in China 2025" prioritize domestic diagnostics. Tax incentives (e.g. cutting VAT on diagnostics from

17% to 13% and a 15% income tax for high-tech firms) and R&D funding programs have stimulated local innovation. Hundreds of IVD companies have been founded, with dozens listed on stock exchanges.

China's rapid build-out of healthcare infrastructure (expanded insurance coverage, billions of screenings) has fueled demand for diagnostics. The government actively subsidizes diagnostics companies and procurement in public hospitals. At the same time, China's regulatory system has tightened: after merging health agencies in 2017–18, product approvals became stricter and slower (new IVD registrations fell ~20%/year). However, these reforms align Chinese standards with global norms

Perhaps the most crucial of drivers for the growth of IVD in China is the overall push for indigenous manufacturing – starting with the designation of special economic zones (SEZs) in the 90s to the identification of Strategic Emerging Interest (SEI) sectors in the 2010s, such as biomedicine, next-gen IT and advanced manufacturing. These have ensured China's transformation from an erstwhile low-cost, labor-intensive export economy to a high-innovation world-class manufacturing economy.

5.5 Conclusion

India's IVD industry can draw actionable insights from each of these models. For example, adopting fiscal incentives and R&D support (as in Ireland/USA) could boost innovation, while strong regulatory frameworks (US/FDA-like and EU-aligned) can ensure quality and market trust.

By combining elements – such as India's own R&D credits and "Make in India" incentives with streamlined registration processes (like a CLIA-waiver path) and dedicated funding programs – India can accelerate its point-of-care and AI-driven diagnostics capabilities. Emulating global best practices in tax policy, regulatory efficiency, and public–private R&D partnerships will be critical for India to build a competitive, innovation-led IVD ecosystem.

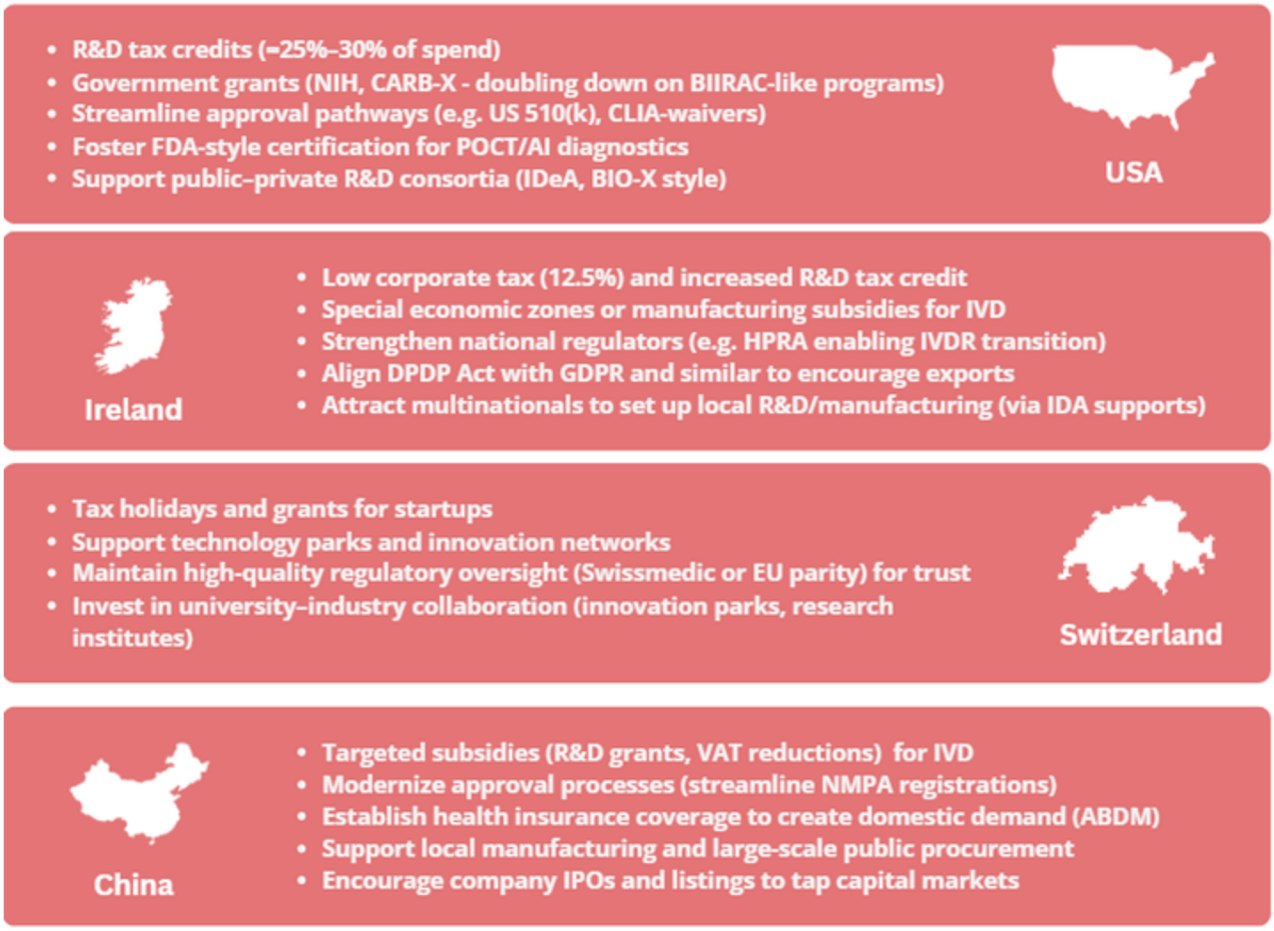

Fig 4. Key takeaways for the Indian IVD Ecosystem

6. State of the ecosystem: Founder's Lens

Startups and startup founders are the cornerstone to cement India's position as a leader in new-age IVDs. As part of benchmarking efforts to assess the current pulse of the ecosystem, conversations were conducted with two founders: Hardik Sharma of Adsys and Manasi Khasnis of BiomarkIQ.

Hardik Sharma
Co-founder, Adsys

Type: Point-of-care/ lab-on-chip systems

Adsys represents a new generation of Indian blood diagnostics startups attempting to build credible, scalable hardware IVD platforms in a cautious market. Backed by ~₹3.8 CR from Rainmatter and Social Alpha, along with grant support from BIRAC and others, the company is navigating the familiar early-stage medtech balancing act: grants for de-risking, equity for growth.

Type: Multi-omics / Multi-marker Diagnostics

BioMarkIQ is building a serum-based, AI-enabled liquid biopsy test for real-time cancer detection. Unlike hardware-heavy IVD players, the company is able to leverage existing CLIA analyzers and cloud-based ML models, reducing capital intensity. The company has raised ~₹2.2 CR through grants and equity-linked instruments and has initiated clinical validation with Tata Memorial Hospital.

Manasi Khasnis
Co-founder, BiomarkIQ

Despite being from markedly different diagnostic sector, both founders highlighted similar journeys and challenges.

> Working with funders who actually understand the healthcare space in India and who are able to make ecosystem connections is critical for startup founders to scale. We are fortunate to have such investors.
>
> *-Hardik Sharma, Adsys*

- **Grant-first de-risking:** Grants such as BIRAC and state-specific grants are the first port-of-call for many entrepreneurs. Venture capital remains hesitant until regulatory clarity and clinical validation are established.
- **Investor literacy gap:** There is a mismatch between funds and startups, re: regulatory timelines, reimbursement pathways, and long gestation cycles in IVD.
- **Regulatory ambiguity:** CDSCO has made great strides in streamlining pathways for regulatory approval. However, the pathways are still evolvinng.
- **Clinical access bottlenecks:** There is a cohort of clinicians and hospital systems that are very open to working with new innovations. However, founders are more or less asked to independently secure hospital partners, navigate ethics approvals, and build doctor trust.
- **Speed mismatch:** Founder execution velocity often outpaces grant disbursal, regulatory reviews, and institutional processes.

> It took us more than a year to build out a relationship with our clinical partner from scratch. There is now a great amount of trust, but it would have been good to have an ecosystem to faciliate a quicker path.
>
> *-Manasi Khasnis, BiomarkIQ*

- **Talent acquisition:** Talent clusters are strong in certain areas like Bangalore and Delhi NCR, but thinner in Tier 2/ Tier 3 cities
- For hardware startups like Adsys, **manufacturing ecosystem constraints** show up - precision tolerances, supply-chain dependencies, and regional talent clustering (e.g., southern bio-clusters outperforming others).

These conversations strongly suggest India has the technical talent and early capital scaffolding to build a sunrise IVD sector - but ecosystem velocity, regulatory clarity, and specialized capital remain the unlocking levers that need intervention.

7.The way forward

In-vitro diagnostics are an integral part of leapfrogging India's healthcare system into the future. Globally, IVDs still are under-utilized with most of the investment and policy still being focused on therapeutics and cures. India has a real chance to emerge as a global IVD leader by aligning standards with global best practices - and expands insurance coverage, its transformative diagnostic technologies (point-of-care chip systems, multi-omics diagnostics, and AI-augmented tools) still demand supportive measures. Coordinated clinician incentives, patient capital, and an investment climate are all equally critical to unlocking their full value in healthcare outcomes.

Clear regulatory pathways

India has taken important steps, introducing the 2017 Medical Device Rules to classify IVDs by risk (Classes A–D) and creating an IVD "Innovators Handbook" (ICMR–CDSCO MedTech Mitra) to guide clinical validation and compliance. These efforts signal commitment, but further clarity is needed on timelines and fast-tracks. For instance, the U.S. FDA's Breakthrough Device program accelerates review of novel diagnostics, offering sprint interactions and priority review for high-impact IVDs. India could emulate this by defining expeditious paths for multi-omic and chip-based tests (e.g. provisional approvals tied to post-market data) to ensure promising technologies reach patients without undue delay while maintaining safety. Harmonizing Indian standards with global norms (IMDRF, IVDR) will also build trust and facilitate exports.

Outcome-focused clinician incentives:

Adoption of advanced diagnostics by doctors hinges on aligning incentives with patient outcomes. Currently, fee-for-service models give little reward for employing costly multi-omic or AI tools unless directly billable. Policymakers should consider value-based payments and coding updates. For example, the U.S. has added nearly 300 new CPT codes for 2026 – 27% of which cover proprietary lab analyses and category-III (emerging) services – explicitly recognizing novel tests in reimbursement. Similarly, outcome-driven pilots (e.g. India's AB-HWC telemedicine or private insurance pilots) could link physician payment to improved diagnostic accuracy or reduced downstream costs. Academic models even propose tying reimbursement to the "degree of AI contribution" in diagnostics, rewarding tools that measurably improve decision-making. Adopting such frameworks would encourage clinicians to use next-gen IVDs (thus delivering "more biology per rupee") by sharing in the value they create through better patient outcomes.

Policy and insurance optimization

India's IVD industry can draw actionable insights from each of these models. For example, adopting fiscal incentives and R&D support (as in Ireland/USA) could boost innovation, while strong regulatory frameworks (US/FDA-like and EU-aligned) can ensure quality and market trust.

By combining elements – such as India's own R&D credits and "Make in India" incentives with streamlined registration processes (like a CLIA-waiver path) and dedicated funding programs – India can accelerate its point-of-care and AI-driven diagnostics capabilities. Emulating global best practices in tax policy, regulatory efficiency, and public–private R&D partnerships will be critical for India to build a competitive, innovation-led IVD ecosystem.

Fig 5. Policy and investment suggestions

Patient capital and exit pathways

Long-term investment and clear exits are key to sustaining innovation. India has attracted record funds into healthcare but medtech still needs more dedicated “patient” capital (long-horizon investors). The government can support this through blended-finance vehicles or by relaxing rules to allow greater FDI in biotech.

Importantly, start-ups need defined routes to scale or exit: the acquisition of diagnostic assets by incumbents. India is seeing many such exits in diagnostic services – such as PharmEasy’s $600 million purchase of Thyrocare (a leading pathology network) in 2021 and Orange Health’s $12M round led by Amazon, However, the country still lags in notable exits or fundraises by novel IVDs. In the US, it is common to see services incumbents or large companies acquire novel diagnostics – recent examples being Quest Diagnostics acquisition of Path AI and Abbott’s acquisition of Exact Sciences. India needs to map and encourage similar pathways – encouraging partnerships, mergers or strategic investments between start-ups and hospitals or pharma/diagnostic giants. Ireland’s model shows the power of public–private collaboration: agencies like Enterprise Ireland partner with multinationals (e.g. Roche) to incubate diagnostics ventures, nurturing firms until they reach exit-readiness. Emulating this, along with fostering strong domestic incumbent champions (e.g. through “Make in India” initiatives and export incentives), will assure investors of eventual returns.

By advancing these four pillars – streamlined regulation, outcome-aligned incentives, optimized insurance policies, and robust financing/exit ecosystems – India can achieve “more biology per rupee”. In other words, patients will benefit from richer diagnostic information delivered more cheaply, and investors and providers will see clearer rewards for innovation. The experiences of peer countries underscore that coordinated policy action (from FDA-style pathways to public insurance reforms and incubator programs) can unlock this potential. Careful adaptation of these lessons to India’s context will be essential for next-generation IVDs to realize their full impact on public health and industry growth.

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Appendix: Detailed Case Study

Economic Impact of IVD-Based Early Screening for Chronic Kidney Disease (CKD) in India

Executive Summary

In vitro diagnostics (IVDs) for CKD screening, such as serum creatinine, blood urea nitrogen (BUN), and urine albumin-to-creatinine ratio (UACR), enable early intervention, averting progression to end-stage renal disease (ESRD) requiring costly dialysis or transplants. As of February 2026, Chronic Kidney Disease (CKD) has emerged as a critical threat to India's fiscal and public health stability, affecting approximately 15–16% of the adult population. The current national strategy is "back-heavy," characterized by a "Dialysis Trap" where the majority of public funds are directed toward End-Stage Renal Disease (ESRD) care through the Pradhan Mantri National Dialysis Programme (PMNDP). [1][2]

This case study models the health economics of nationwide IVD screening for high-risk groups in India, leveraging data from the Pradhan Mantri National Dialysis Programme (PMNDP) and prevalence studies. Using conservative public-sector costings, the model demonstrates that this "Screen-to-Manage" approach can avert ~3.2 million ESRD cases over ten years. The program reaches a fiscal break-even point by Year 6–7, transforming a recurring, non-discretionary liability into a sustainable investment with a Benefit-Cost Ratio (BCR) of approximately 2.2:1. Early detection aligns with public health policy, reducing morbidity and aligning with PMNDP's free dialysis for below-poverty-line (BPL) patients.

Background on CKD Burden in India

India's kidney care crisis is driven by late detection; approximately 90% of patients remain unaware of their condition until they reach Stage 4 or 5. This necessitates immediate, life-sustaining dialysis.

The PMNDP Fiscal Reality

PMNDP, launched in 2016, provides free hemodialysis (3 sessions/week) to BPL patients via public-private partnerships, serving over 17 lakh beneficiaries. Private dialysis costs ₹24,000-50,000 monthly, while transplants range ₹5-15 lakhs.[7][8][4][9]

IVDs like creatinine-based eGFR (₹200-400) detect stages 1-3, where management (e.g., ACE inhibitors) slows progression by 20-50%.[10][11] Under the PMNDP's Public-Private Partnership (PPP) model, the government incurs significant costs to maintain a single ESRD patient:

- Dialysis Sessions: At ₹1,274–₹1,500 per session, a patient requiring 2–3 sessions per week costs the state approximately ₹1.3 to ₹1.8 lakhs annually in direct session fees alone.
- Secondary/Ancillary Costs: Essential medications (Erythropoietin, iron), lab work, and hospitalizations for fluid overload or infections add an estimated ₹60,000 to ₹70,000 per year.
- Total Public Liability: The conservative total cost per ESRD patient is approximately ₹2.0 lakhs per year.

Objectives and Scope

This case study evaluates the cost-benefit of IVD screening for high-risk cohorts (diabetics, hypertensives; ~10-20% of adults) versus no screening, focusing on averted ESRD costs over three years. It extrapolates national figures from regional data (e.g., Telangana: ₹60 crore screening saves ₹1,100 crore).[2] Scope excludes indirect costs (lost productivity) and long-term (>3 years).[2]

Methodology and Key Assumptions

This study employs a 10-year budget-impact horizon, focusing on 100 million adults with diabetes or hypertension already registered under the National Programme for Prevention and Control of Non-Communicable Diseases (NP-NCD).

Assumptions (Calibrated for 2026 Public Sector Rates)

The model rejects private market rates in favor of government procurement realities:

- Target Cohort: 100 million high-risk individuals.
- CKD Prevalence: 16% of the screened cohort (16-17 million people).
- IVD Screening Cost: ₹150–₹200 per person annually, assuming centralized national tendering.
- Incremental Management Cost: ₹3,000 per patient/year for primary care-level management (ACEi/ARB pharmacotherapy and BP control at Health and Wellness Centres).
- ESRD Aversion Rate: A conservative 20% reduction or delay in progression to ESRD through early intervention.
- Avoided Cost: ₹2.0 lakhs per year per averted ESRD case.

Formulas for Economic Modeling

1. ESRD cases without intervention: ESRD_without = Screened*Prev*Risk*Coverage4
2. Prevented ESRD cases: Prevented = ESRD_without*Avert_rate
3. Savings per prevented case: Savings_case = Dialysis_monthly - (Early_monthly*12* Years
4. Annual Investment (I): I = Cohort*Cost_Screen + CKD_Prevalence*Cost_Mgmt
5. Annual Savings (S): S = (Cumulative ESRD Cases Averted)*Cost_Dialysis
6. Net Fiscal Impact (NFI):NFI = S - I
7. Benefit-Cost Ratio (BCR): BCR = Cumulative Savings (Sum_S) / Cumulative Investment (Sum_I)

A deterministic cohort model calculates net benefits using prevalence, progression rates, and costs sourced from peer-reviewed studies and government reports. [11] [12] [13]

Assumptions and Extrapolations

- Population
  - Adult population: 1 billion (15+ years).
  - Target Cohort: 100 million high-risk individuals. CKD prevalence: 16%ESRD progression risk (no intervention): 30% over 3 years (extrapolated from stage data).

- Intervention
  - Screening coverage: 50% of high-risk (100M cohort).[extrapolation]
  - IVD Screening Cost: ₹150–₹200 per person annually (assuming centralized national tendering)
  - Dialysis monthly: ₹30,000 (PMNDP/private blend).
  - Incremental Management Cost: ₹3,000 per patient/year for primary care-level management (ACEi/ARB pharmacotherapy and BP control at Health and Wellness Centres).
- Outcome
  - Aversion rate: 20% (early management).
  - Horizon: 3 years; screening phased annually (total ₹120 crore).
  - No discounting (short horizon); ignores transplants (10-20% of ESRD).[extrapolation]
  - Avoided Cost: ₹2.0 lakhs per year per averted ESRD case.
- Clinical
  - Progression Attenuation: Early management at the HWC level (Stage 1–3) is assumed to avert or significantly delay ESRD in roughly 20% of the cohort over a 10-year horizon.
  - Ramp-up Effect: Savings are back-loaded because it takes 2–3 years of management to "bend the curve" of progression.

Component	Public-Sector Cost	Context/Implementation Detail
Target Annual IVD Screening (Reduced with volume from ₹1000)	**₹400 per person**	Includes Creatinine/eGFR, UACR kits, logistics, and digital data entry into the CPHC-NCD/ABHA platform.
Early Management	**₹15,000 per patient**	Covers protocol-based medication titration (ACEi/ARBs), counseling, and Mid-Level Health Provider (MLHP) training.
Max Total Annual Investment (scaled over 10 years)	**₹64,000 Crore**	Based on screening 100M people and managing 16M CKD cases.

The Intervention: "Screen-to-Manage"

A core principle of this case study is that screening without a management protocol is a "waste of diagnostic resources".

Implementation Roadmap Modeling

- Phase 1: Procurement (Months 1-6): Utilize the Government e-Marketplace (GeM) for centralized kits, driving costs to the target ₹150–₹200 range.
- Phase 2: Capacity Building (Months 6-18): Task-shift CKD management to 1.5 lakh Mid-Level Health Providers (MLHPs) and ASHAs. Training focuses on salt reduction, NSAID avoidance, and medication adherence.
- Phase 3: Digital Integration: Link results to the Ayushman Bharat Health Account (ABHA) to identify "rapid progressors" and prevent duplicate testing.

Model Results

For a 100 million high-risk cohort. By increasing the screening cost to ₹400 and factoring in comprehensive management, the "upfront" investment is higher, pushing the break-even point deeper into the decade—a timeline more attractive to NITI Aayog's medium-term fiscal planning.

Time Point	Annual Program Investment	Cumulative ESRD Cases Averted	Annual Public Savings (Avoided Care)	Net Fiscal Impact	Benefit-Cost Ratio (BCR)
Year 1	₹28,000 Cr	~150,000	₹3,000 Cr	-₹25,000 Crore (Deficit)	**0.11 : 1**
Year 3	₹28,000 Cr	~750,000	₹16,500 Cr	-₹13,000 Cr (Deficit)	**0.59 : 1**
Year 5	₹28,000 Cr	~1,200,000	₹24,000 Cr	-₹4,000 Cr (Closing Gap)	**0.86 : 1**
Year 7	₹28,000 Cr	~1,800,000	₹36,000 Cr	+₹8,000 Cr (Break Even around Year 6)	**1.28 : 1 (Break-Even)**
Year 10	₹28,000 Cr	~3,200,000	₹64,000 Cr	+₹36,000 Cr (Surplus)	**2.28 : 1**

Sensitivity Analysis

Parameter	Base Value	Low (-20%)	High (+20%)	Impact on BCR & Break-Even
Aversion Rate	20%	16%	24%	**High Impact**: A 16% rate pushes break-even to Year 9.
Dialysis Cost	₹2.0L	₹1.6L	₹2.4L	**Moderate**: Lower costs reduce the "dividend" of prevention.
Screening/Implementation	₹400	₹320	₹480	**Low**: Even at ₹480, the BCR remains robust due to high ESRD costs.
Progression Risk	30%	24%	36%	**Moderate**: Higher risk in the cohort leads to faster ROI.

The Telangana Pilot Proxy

The feasibility and fiscal rationale of the "Screen-to-Manage" model are grounded in real-world data from the Telangana pilot (2025). This regional evidence provides a high-confidence proxy for how targeted IVD investment transforms public health outcomes.[2]

The pilot demonstrates the following key pillars:

- The Fiscal Disparity: Nephrologists in the region demonstrated that a targeted investment of ₹60 Crore in early screening could avert approximately ₹1,100 Crore in downstream dialysis costs.
- High-Yield Targeting: The screening focused on the "danger signals" of lifestyle-driven CKD, identifying that 22% of high-risk individuals were diabetic and 23% had high blood pressure.
- Detection of "Silent" Progression: The pilot successfully identified patients at Stage 1 CKD, who were largely asymptomatic and otherwise would not have sought care until reaching kidney failure.
- Environmental Risk Mapping: The methodology identified localized risk factors, such as high fluoride levels in Nalgonda and heat-induced dehydration in rural farming communities, allowing for geographically targeted management.
- Policy Integration: The pilot recommended expanding the National Programme for Prevention and Control of Non-Communicable Diseases (NP-NCD) to include eGFR and UACR as standard diagnostic requirements.

Strategic Advantages and Policy Implications

IVD screening is highly cost-effective, supporting integration into Ayushman Bharat and PMNDP. Prioritize high-risk groups to maximize BCR; subsidize IVDs (₹250 with implementation costs around ₹250) for scale.

Implementing this IVD-led strategy provides three critical benefits beyond direct fiscal savings:

1. Infrastructure Preservation: Every averted case reduces the physical demand for a dialysis bed, nurse, and machine—resources currently at a breaking point in rural districts. This prevents the need for ~30,000 new dialysis machines over the next decade.
2. Equity and Medical Bankruptcy: Dialysis is a leading cause of Catastrophic Health Expenditure (CHE) in India; prevention protects families from medical bankruptcy.
3. Fiscal Sustainability: By "flattening the curve" of new dialysis entrants, the PMNDP budget remains viable for those who truly require renal replacement therapy.

Key Recommendations

The initial plan suggests more evidence is needed but it supports a move from "health as an expense" to "health as a strategic investment".

- Pilot: Launch a Phase-1 pilot in 5 high-burden states (e.g., Kerala, Tamil Nadu, Maharashtra) to validate the ₹150 bulk pricing and measure protocol adherence.
- Fiscal Shift: Reallocate a percentage of future PMNDP expansion funds into "Front-End" diagnostics to stabilize long-term debt.
- Mandatory Testing: Integrate annual eGFR/UACR testing as a mandatory component for all diabetic/hypertensive patients under NP-NCD.
- Mandatory ABHA Sync: Ensure diagnostic results are linked to the Ayushman Bharat Health Account to prevent duplicate testing and guide longitudinal care.
- Bulk Procurement: Leverage the Government e-Marketplace (GeM) for national tenders to drive kit prices toward ₹150–₹200, creating further fiscal cushion.
- HWC Protocolization: Task MLHPs at Health and Wellness Centres with Stage 1–3 management, reserving specialists for Stage 4+ to maintain the primary care cost-advantage

Conclusion

By accounting for a realistic Year 6 break-even, the model becomes highly defensible for NITI Aayog's medium-term fiscal planning. It moves the policy narrative from "unavoidable expenditure" to "managed investment," where the high BCR justifies the initial annual investment of ₹28,000 Crore. IVDs transform CKD from a cost sink into a preventable burden, with a long-term BCR reaching 2.28:1 (approaching 3:1 in optimized scenarios), justifying a nationwide policy rollout. Scaling this intervention could save the national exchequer billions by averting or delaying 3.2 million ESRD cases over the next decade.

For the Indian state, the choice is no longer between screening and dialysis; it is between planned prevention today and unsustainable dialysis debt tomorrow.

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